

PATENT COOPERATION TREATY

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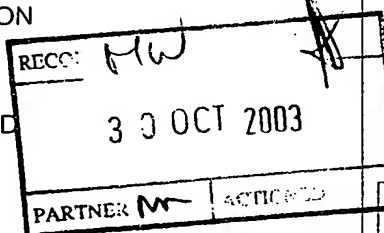
19 JUL 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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WRITTEN OPINION
(PCT Rule 66)

Date of mailing
(day/month/year)

28.10.2003

Applicant's or agent's file reference
TECU/P27639PC

REPLY DUE

within 2 month(s)
from the above date of mailing

International application No.
PCT/EP03/00517

International filing date (day/month/year)
17.01.2003

Priority date (day/month/year)
19.01.2002

International Patent Classification (IPC) or both national classification and IPC
A61B8/14

Applicant

STICHING VOOR DE TECHNISCHE WETENSCHAPPEN et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 19.05.2004

Name and mailing address of the international preliminary examining authority:



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WRITTEN OPINION

International application No. PCT/EP03/00517

I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-13 as originally filed

Claims, Numbers

1-29 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this opinion.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 28-29

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 28-29 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-27
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Inventive step (IS)	Claims	
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Industrial applicability (IA)	Claims	
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2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 28 and 29 attempt to define the relevant subject-matter with reference to the drawings only. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is certainly not the case here. In order to overcome this objection claims 28 and 29 should be deleted.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. In order to avoid any objection under Rule 67.1(iv) PCT concerning methods for treatment of the human or animal body by surgery, the features of dependent claim 8 should be incorporated into the independent method claim 1. The following opinion is given assuming that claim 1 has been amended to involve this feature.
3. Although method claim 9 and apparatus claim 23 have been drafted as independent claims, they comprise all the features of the independent claims 1 and 18 respectively. Claims 9 and 23 should therefore be formulated as claims dependent on the latter (Rule 6.4 PCT).
4. Reference is made to the following document:

D1: US-A-5 928 151 (HOSSACK JOHN A ET AL) 27 July 1999
5. Concerning the independent claims of the present application the following is noted.
 - 5.1. The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

Document D1, which the references in parentheses apply to, discloses (see

abstract) a method for ultrasound imaging comprising the steps of:

- transmitting ultrasound energy into a target volume at at least a first fundamental frequency (see abstract, lines 2-4);
- receiving reflected and/or scattered ultrasound energy from the target volume (see abstract, lines 6-8); and
- detecting components of the received signal at multiple harmonics of the fundamental frequency (see col. 4, lines 64-66).

Consequently, document D1 discloses the combination of features in claim 1, whose subject-matter is not new (Art. 33(2) PCT).

- 5.2. Independent claim 18 defines the apparatus to carry out the method defined in claim 1. Consequently, the arguments presented under point 5.1 can be applied mutatis mutandis to the subject-matter of claim 18, which accordingly is not new (Art. 33(2) PCT).
6. The additional features of the dependent claims 2 to 17 and 19 to 27 of the present application are already known from the available prior art or relate to minor constructional changes which come within the scope of customary practice followed by persons skilled in the art. These claims would be allowable only if they referred to an independent claim, which meets the requirements of the PCT with respect to novelty and/or inventive step (see Rule 6 PCT).

The following points should be considered when filing amendments:

- A) Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).
- B). In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of

the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). The applicant's attention is drawn to the fact that any amendments, whose origin is not clearly indicated, may not be taken into consideration for the establishment of the international examination report. Furthermore, a new set of claims involving an unnecessary plurality of independent claims will lead to no examination of any of the claims being carried out.